

What is claimed is:

1. A method of treating heart failure and/or renal failure in a patient, comprising delivering to said patient CGRP in an amount effective to provide symptomatic relief, prevent exacerbation of symptoms, and/or prevent and/or delay progression of the disease state of heart failure in said patient, wherein said CGRP is delivered to said patient as a controlled release composition.
2. The method of claim 1, wherein said controlled release composition comprises a flowable thermoplastic polymer composition comprising a biocompatible polymer, a biocompatible solvent and CGRP and said composition is delivered to a bodily tissue or fluid in said patient, wherein the amounts of the polymer and the solvent are effective to form a biodegradable polymer matrix containing CGRP in situ when said composition contacts said bodily fluid tissue or fluid.
3. The method of claim 1, wherein said CGRP is in the form of a conjugate comprising CGRP coupled to a polymer.
4. The method of claim 3, wherein said polymer is a poly(alkylene glycol) or a polysaccharide.
5. The method of claim 2, wherein the composition further comprises a controlled release additive.
6. The method of claim 2, wherein said CGRP is released from said polymer matrix at a rate that will maintain circulating plasma levels of CGRP between  $11 \pm 5$  pg/ml and  $186 \pm 127$  pg/ml over a period of 7 to 180 days.
7. The method of claim 6, wherein said composition comprises between about 0.56 and 290 mg CGRP and between about 0.01 and 5.8 mL of said composition is administered to said patient.
8. The method of claim 6, wherein said composition comprises about 0.56 and 290 mg CGRP and between about 0.004 and 1.93 mL of said composition is administered to said patient.
9. The method of claim 2, wherein said biocompatible polymer is selected from the group consisting of polylactides, polyglycolides, polyanhydrides, polyorthoesters, polycaprolactones, polyamides, polyurethanes, polyesteramides, polydioxanones, polyacetals, polyketals, polycarbonates, polyorthocarbonates, polyphosphazenes, polyhydroxybutyrates, polyhydroxyvalerates, polyalkylene oxalates, polyacrylates,

- polyalkylene succinates, poly(malic acid), poly(amino acids) and copolymers, terpolymers, cellulose diacetate, ethylene vinyl alcohol, and copolymers and combinations thereof.
10. The method of claim 2, wherein the polymer matrix releases CGRP by diffusion, erosion, or a combination of diffusion or erosion as the polymer matrix biodegrades in said patient.
  11. The method of claim 2, wherein said CGRP is delivered via a puncture needle or catheter.
  12. The method of claim 2, further comprising administering one or more drugs selected from the group consisting of anti-proliferative agents, anti-clotting agents, vasodilators, diuretics, beta-blockers, calcium ion channel blockers, blood thinners, cardiotonics, ACE inhibitors, anti-inflammatories, and antioxidants.
  13. The method of claim 12, wherein said drug is added to said polymer composition prior to administration such that said solid polymer matrix further contains said drug.
  14. The method of claim 12, wherein said drug is administered as a separate formulation before, simultaneously, or subsequently to administration of said polymer composition.
  15. The method of claim 1, wherein said treatment is provided as a prophylaxis to prevent or delay further progression of said heart failure and/or said renal failure.
  16. The method of claim 1, wherein the length of said treatment is sufficient to relieve or attenuate one or more symptoms of heart failure.
  17. The method of claim 1, wherein said treatment is sufficient to improve renal blood flow, glomerular filtration rates, and/or serum levels of urea and creatinine in said patient.
  18. The method of claim 1, wherein said treatment is sufficient to improve the quality of life of said patient.
  19. The method of claim 1, wherein said patient is a pediatric patient.
  20. The method of claim 1, wherein said controlled release composition comprises biodegradable microspheres incorporating CGRP.
  21. The method of claim 20, wherein said microspheres comprise poly(lactic-co-glycolic acid), poly(lactic acid), poly(caprolactone), polycarbonates, polyamides, polyanhydrides, polyamino acids, polyortho esters, polyacetals, polycyanoacrylates

degradable polyurethanes, polyacrylates, ethylene-vinyl acetate copolymers, acyl substituted cellulose acetates, and derivatives and copolymers thereof.

22. The method of claim 20, wherein said CGRP is in the form of a conjugate comprising CGRP coupled to a polymer.
23. The method of claim 20, wherein said microspheres are embedded in a gel matrix.
24. The method of claim 1, wherein said controlled release composition comprises CGRP encapsulated in a liposome.
25. The method of claim 23, wherein said CGRP is in the form of a conjugate comprising CGRP coupled to a polymer.
26. The method of claim 23, wherein said polymer is a poly(alkylene glycol) or a polysaccharide.
27. The method of claim 1, wherein said controlled release composition comprises CGRP conjugated to a polymer.
28. The method of claim 1, wherein said controlled release composition is in film form.
29. The method of claim 28, wherein said film comprises polylactic acid, polyglycolic acid and mixtures and copolymers thereof.
30. A method of treating heart failure and/or renal failure in a patient, comprising administering a flowable composition comprising a biocompatible polymer, a biocompatible solvent and CGRP to a bodily tissue or fluid in said patient, wherein the amounts of the polymer and the solvent are effective to form said polymer matrix comprising CGRP in situ when the formulation contacts said bodily fluid tissue or fluid wherein polymer matrix comprises between about 5% and 15% CGRP by weight and said CGRP is released from said polymer matrix at a rate between about 0.0008 and 0.016  $\mu\text{g}/\text{min}/\text{kg}$  body weight over a period of 7 to 180 days.
31. A method of treating heart failure and/or renal failure in a patient, comprising:
  - (a) administering CGRP to said patient by a method selected from parenteral, oral, sublingual, intranasal, intracoronary, intra-arterial, intravenous, transmucosal, or intradermal delivery for a time and at a dose effective to provide symptomatic relief, prevent exacerbation of symptoms, and/or prevent and/or delay progression of the disease state of heart failure in said patient; and
  - (b) delivering CGRP to said patient as a controlled release formulation in an amount effective to provide symptomatic relief, prevent exacerbation of symptoms, and/or prevent and/or delay progression of the disease state of heart failure in said patient.

32. The method of claim 31, wherein said controlled release formulation comprises a flowable thermoplastic polymer composition comprising a biocompatible polymer, a biocompatible solvent and CGRP and said composition is delivered to a bodily tissue or fluid in said patient, wherein the amounts of the polymer and the solvent are effective to form a biodegradable polymer matrix containing CGRP in situ when said composition contacts said bodily fluid tissue or fluid.
33. The method of claim 31, wherein said controlled release formulation comprises biodegradable microspheres incorporating CGRP.
34. The method of claim 31, wherein said controlled release formulation comprises wherein said controlled release composition comprises g CGRP encapsulated in a liposome.
35. The method of claim 31, wherein said controlled release formulation comprises CGRP coupled to a polymer.
36. The method of claim 31, wherein said controlled release formulation is in film form.
37. A method of preventing or reducing the risk of occurrence of myocardial infarction, comprising delivering to a human at risk of having a myocardial infarction a controlled release formulation of CGRP comprising an amount of CGRP effective to prevent or reduce the risk or occurrence of myocardial infarction.
38. The method of claim 37, wherein said controlled release formulation comprises a flowable formulation comprising a biocompatible polymer, a biocompatible solvent and CGRP wherein said formulation is delivered to a bodily tissue or fluid in said patient and a solid polymer matrix containing said CGRP is formed in situ in said tissue or fluid.
39. The method of claim 37, wherein said controlled release formulation comprises biodegradable microspheres incorporating CGRP.
40. The method of claim 37, wherein said controlled release formulation comprises wherein said controlled release composition comprises g CGRP encapsulated in a liposome.
41. The method of claim 37, wherein said controlled release formulation comprises CGRP coupled to a polymer.
42. The method of claim 37, wherein said controlled release formulation is in film form.

43. A kit comprising a first container comprising a controlled release formulation of CGRP, said formulation comprising an amount of CGRP effective to treat or prevent heart failure and/or renal failure.
44. The kit of claim 43, further comprising one or more drugs selected from the group consisting of anti-proliferative agents, anti-clotting agents, vasodilators, diuretics, beta-blockers, calcium ion channel blockers, blood thinners, cardiotonics, ACE inhibitors, anti-inflammatories, and antioxidants.
45. The kit of claim 29, further comprising a second container comprising one or more drugs selected from the group consisting of anti-proliferative agents, anti-clotting agents, vasodilators, diuretics, beta-blockers, calcium ion channel blockers, blood thinners, cardiotonics, ACE inhibitors, anti-inflammatories, and antioxidants.
46. The kit of claim 29, further comprising a puncture needle or catheter.
47. A method of counteracting ischemia due to myocardial infarction in a patient, comprising delivering to said patient an amount of CGRP effective to provide cardioprotection, reduction in infarction size, reduction in reperfusion injury, symptomatic relief, and/or prevent exacerbation of symptoms, wherein said CGRP is delivered to said patient as a controlled release composition.